

Remarks

Reconsideration and withdrawal of the objections to the specification and rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 31-34, 36, 39, 41, and 61-62 are amended, and claim 63 is added. Claims 29-58 and 61-63 are pending. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims prior to amendment, which claims are present in a continuation of the present application.

Amended claims 31-32 and 62 are supported at page 7, lines 15-18 and page 72, lines 31-32.

Amended claim 33 is supported at page 7, lines 3-18.

Amended claims 34 and 36 are supported at page 7, lines 3-18 and Figure 31.

Amended claim 39 is supported in Example 10.

Amended claims 41 and 61 are supported at page 8, line 26-page 9, line 3, and in Example 10.

Amended claim 62 and new claim 63 are supported at Figure 31, the SEQUENCE LISTING, page 7, lines 15-18 and page 72, lines 31-33.

The present claims are entitled to the filing date of U.S. application Serial No. 09/105,537, i.e., June 26, 1998, now U.S. Patent No. 6,265,202, as a sequence having a *pikA* promoter and a *pikAV* gene (encoding a thioesterase II) from a *met/pik* PKS gene cluster is disclosed therein (see, e.g., Figures 28-29 and 31, column 22, lines 60-61, and Table 2).

The Title and Brief Description of Figure 41 are amended in response to the Examiner's objections in items 7 and 9, respectively, in the Office Action dated December 16, 2004.

With respect to the amended Abstract, it is Applicant's position that the amended Abstract is in compliance with MPEP § 608.01(b) as a source organism, i.e., *Streptomyces*, is mentioned therein. The specification discloses that *Streptomyces* spp. are sources of the *met/pik* gene cluster (page 24, lines 8-12).

The 35 U.S.C. § 112, Second Paragraph, Rejections

The Examiner rejected claims 40 and 61 under 35 U.S.C. § 112, second paragraph, as being indefinite, as the claims do not recite the claimed DNA molecule. This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

The *pikA* promoter is found between *pikRI* and *pikAI* in the *met/pik* gene cluster (Figures 28 and 31 and page 72, lines 31-33). Claim 40, which depends on claim 32 and claims dependent on claim 32, is directed to a host cell having an expression cassette in which a *pikA* promoter is linked to an open reading frame. Claim 32 is directed to an expression cassette comprising a promoter sequence having at least 90% nucleic acid sequence identity to a DNA fragment corresponding to a nucleotide sequence between an *EcoRV* site and *EcoRI* site in SEQ ID NO:5 (SEQ ID NO:5 is shown in Figure 31). Therefore, claim 40 is clear.

Claim 61, which depends on claim 40, is directed to a host cell having an expression cassette with a promoter related to the *pikA* promoter in SEQ ID NO:5, in which a chromosomal gene from the *met/pik* gene cluster is deleted or replaced so as to result in altered expression of certain domains encoded by *pikA*, which in turn alters methymycin, pikromycin, neomethymycin, and/or narbomycin production by the host cell (see Example 10). Accordingly, claim 61 is clear.

Thus, withdrawal of the § 112(2) rejections is respectfully requested.

The 35 U.S.C. § 112, First Paragraph, Rejections

The Examiner rejected claims 31-41 and 61 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the specification describes only one species of *pikA* promoter. The Examiner further rejected claims 36, 39-41 and 61 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for the genus of TEII domains, as one of skill in the art would allegedly be unable to predict the structure of other members of the genus in view of the specification. These rejections, as they may be maintained with respect to the pending claims, are respectfully traversed.

To provide an adequate written description for a claimed genus, the specification can provide a sufficient description of a representative number of species by an actual reduction to

practice, reduction to drawings or by a disclosure of relevant, identifying characteristics, i.e., by a structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics (Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112(1) Written Description Requirement, Fed. Reg., 66, 1099 (2001)). Satisfactory disclosure of a representative number depends on whether one skilled in the art would recognize that Applicant was in possession of the necessary common attributes or features of the elements possessed by members of the genus (Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112(1) Written Description Requirement, Fed. Reg., 66, 1099 (2001)).

As amended, claims 31 and 32 recite that the promoter has at least 90% nucleic acid sequence identity to a DNA fragment corresponding to a nucleotide sequence between an EcoRI site and an EcoRV site in SEQ ID NO:5. As amended, claims 34 and 36 recite that the thioesterase has at least 90% amino acid sequence identity with SEQ ID NO:43.

Since the claims recite relevant common functional (a promoter or a thioesterase) and structural characteristics (percent identity to a reference sequence) of the claimed genus of promoters and the claimed genus of thioesterases, the written description requirement of § 112(1) has been satisfied.

Hence, withdrawal of the § 112(1) rejections is respectfully requested.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 16th day of February, 2005.

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